NELLCOR

OPERATOR'S MANUAL

NPB-290 Pulse Oximeter

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

To contact Mallinckrodt's representative: In the United States, call 1.800.635.5267 or 314.654.2000; outside of the United States, call your local Mallinckrodt representative.

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CONTENTS

Figures
Tables

CONTENTS

CONTENTS ..... **iii**
Contents iii
Figures vii
Tables vii
SAFETY INFORMATION **1**
General Safety Information 1
INTRODUCTION ***3***
Intended Use 3
General Operating Principles and Conditions 3
CONTROLS, INDICATORS, AND SYMBOLS **5**
Displays, Controls, Indicators, and Connectors 5
Other NPB-290 Symbols 6
Description of Controls 7
Function Buttons 7
Indicators 7
Description of Visual Indicators and Displays 8
Description of Audible Indicators 8
QUICK GUIDE TO OPERATION **11**
Basic Operation 11
Setup 11
Using the Monitor 12
Adjust Pulse Beep Volume 13
Alarm Functions 13
View/Adjust Alarm Limits 13
Audible Alarm Silence 13
Adjust Alarm Silence Duration 14
Disabling Audible Alarms 14
Adjust Alarm Volume 14
SETUP **15**
Unpacking and Inspection 15
Performance Verification 15

List of Components 15
Optional Accessories 15
Monitor Setup 16
General 16
Setting Up the NPB-290 16
SENSORS AND ACCESSORIES **21**
Selecting a Sensor 21
Biocompatibility Testing 22
Performance Considerations 22
Optional Accessories 24
Wall Mount Plate 24
Tilt-Stand Supports 25
START-UP AND USE **27**
Basic Operation 27
Power-On Self-Test (POST) 28
Silencing or Adjusting Pulse Beep Volume 29
Monitoring 30
Pulse Search 30
Automatic Shutdown 31
Alarms 32
Description of Alarms 32
Adjusting Alarm Limits 33
Adjusting Audible Alarm Silence Duration 35
Disabling Audible Alarms 36
Alarm Silence Reminder 37
Adjusting Audible Alarm Volume 37
Management of Loss-of-Pulse Alarm 37
Nurse Call Feature 41
Trend Data 41
Battery Operation 43
Low Battery Indicator 43
Disposal of Device Components 44
Performance Considerations 44
Impact of Patient Conditions on Monitor Readings 44
TROUBLESHOOTING AND MAINTENANCE **47**
Troubleshooting 47
EMI Interference 50
Obtaining Technical Assistance 51

Returning The NPB-290 51
Maintenance 51
Service 51
Periodic Safety Checks 52
Performance Verification 52
Cleaning 52
SPECIFICATIONS **53**
Performance 53
Measurement Range 53
Accuracy 53
Pulse Rate Display Update Frequency 54
Immunity 54
Electrical 54
Instrument 54
Battery 54
Environmental Conditions 55
Operating Temperature 55
Transport/Storage Temperature 55
Humidity 55
Altitude 55
Environmental Protection 56
Physical 56
Weight 56
Size 56
Equipment Classification 56
APPENDIX A: PRINCIPLES OF OPERATION **57**
Oximetry Overview 57
Automatic Calibration 57
Functional versus Fractional Saturation 58
Measured versus Calculated Saturation 58
APPENDIX B: DATA PORT PROTOCOL **61**
Overview 61
Trend Data 61
Connecting to the DATA Port 62
Real-Time Display Format 64
Column Headings 65
Patient Data and Operating Status 66
Trend Data Printout 68

Trend Data Operation 69
Nurse Call 70
Analog Outputs 70

FIGURES

Figure 1: NPB-290 Front Panel Display 5
Figure 2: NPB-290 Rear Panel 6
Figure 3: Connecting the Power Cord 18
Figure 4: Connecting an MC-10 or SCP-10 Sensor Cable to the NPB-290 19
Figure 5: Attaching the Mounting Plate 25
Figure 6: Attaching the Tilt-Stand Supports 26
Figure 7: Monitoring Conditions and Alarm Responses 39
Figure 8: Oxyhemoglobin Dissociation Curve 59
Figure 9: Serial Port Pin Layout 64
Figure 10: Real-Time Printout 65
Figure 11: Trend Data Printout 69

TABLES

Table 1: Nellcor Sensors 22
Table 2: Data Port Pinouts 63
Table 3: Status Codes 68
Table 4: Analog Pinouts 71

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SAFETY INFORMATION

General Safety Information

GENERAL SAFETY INFORMATION

This section contains important safety information related to general use of the NPB-290 pulse oximeter. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information. Be sure to read all text surrounding all precautionary information.

Specific information about ambient environmental conditions, sensor application, and patient conditions is contained throughout this manual.

Important! Before use, carefully read this manual, accessory directions for use, all precautionary information in boldface type, and specifications.

WARNING: Explosion hazard. Do not use the NPB-290 pulse oximeter in the presence of flammable anesthetics.

WARNING: The NPB-290 is a prescription device and is to be operated by qualified personnel only.

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

Caution: When connecting the NPB-290 to any instrument, verify proper operation before clinical use. Both the NPB-290 and the instrument connected to it must be connected to a grounded outlet. Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 950 for data-processing equipment or IEC Standard 601-1 for electromedical equipment. All combinations of equipment must be in

compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1 and the electromagnetic compatibility standard IEC Standard 601-1-2.

To ensure accurate readings, consider the environmental conditions that are present and the condition of the patient. See the appropriate sections of the manual for specific safety information related to these conditions.

INTRODUCTION

Intended Use
General Operating Principles and Conditions

INTENDED USE

The Nellcor NPB-290 pulse oximeter is intended for continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), and pulse rate (measured by SpO_2 sensor).

The monitor is intended for use on adult, pediatric, and neonatal patients in all hospital areas, hospital-type facilities, and in the home environment. It may be used during intra-hospital transport when powered by its internal battery.

WARNING: The NPB-290 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

GENERAL OPERATING PRINCIPLES AND CONDITIONS

The NPB-290 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Note: For an explanation of functional versus fractional saturation, refer to *Appendix A, Principles of Operation.*

Because a measurement of SpO_2 is dependent on light from the sensor, excessive ambient light can interfere with this measurement.

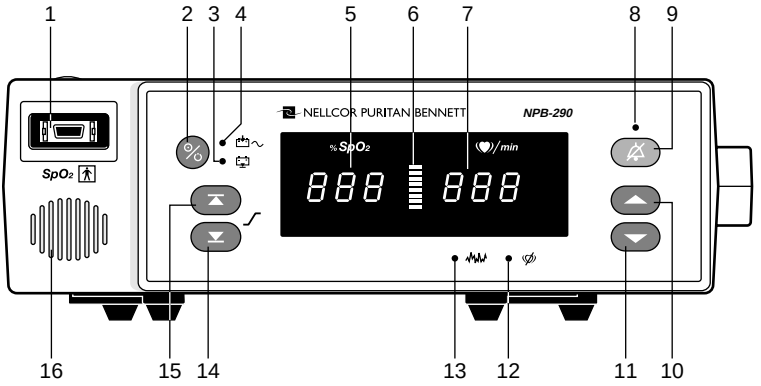
Specific information about ambient environmental conditions, sensor application, and patient conditions, is contained throughout this manual.

CONTROLS, INDICATORS, AND SYMBOLS

Displays, Controls, Indicators, and Connectors
Other NPB-290 Symbols
Description of Controls
Description of Visible Indicators and Displays
Description of Audible Indicators

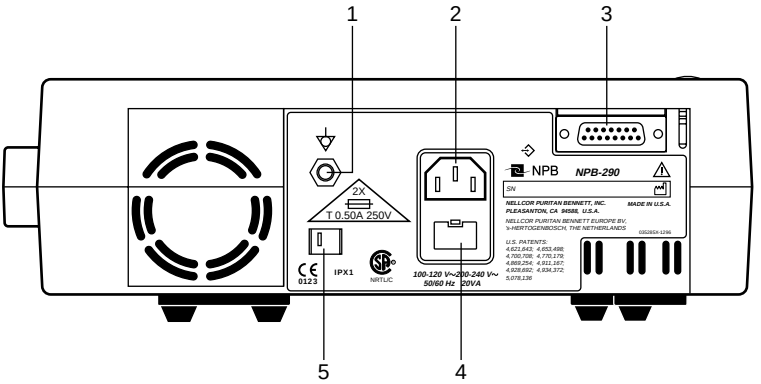
DISPLAYS, CONTROLS, INDICATORS, AND CONNECTORS

Figures 1 and 2 show the front and rear views of the NPB-290 and identify displays, controls, and connectors.



1	SpO_2 Sensor Port	9	Alarm Silence Button
2	Power On/Off Button	10	Adjust Up Button
3	Low Battery Indicator	11	Adjust Down Button
4	AC Power Indicator	12	Pulse Search Indicator
5	%SpO_2 Display	13	Motion Indicator
6	Pulse Amplitude Indicator	14	Lower Alarm Limit Button
7	Pulse Rate Display	15	Upper Alarm Limit Button
8	Alarm Silence Indicator	16	Speaker

Figure 1: NPB-290 Front Panel Display



1 Equipotential Terminal
2 AC Connector
3 Data Port Connector
4 Fuse Receptacle
5 Supply Voltage Selector Switch

Figure 2: NPB-290 Rear Panel

OTHER NPB-290 SYMBOLS

See Instructions for Use

Fuse Replacement

Date of Manufacture

Data Interface

Equipotential Terminal

Type BF Applied Part — Not Defibrillator-Proof

DESCRIPTION OF CONTROLS

Function Buttons

The Power On/Off button. Used to turn the NPB-290 monitor on or off.

The Alarm Silence button. Used to silence current alarms for the alarm silence duration period. It is also used to view and adjust alarm silence duration and the alarm volume.

The Adjust Up button. Used to increase alarm limit values, alarm silence duration, as well as alarm and pulse beep volumes. Also used to scroll through menu items.

The Adjust Down button. Used to decrease alarm limit values, alarm silence duration, as well as alarm and pulse beep volumes. Also used to scroll through menu items.

The Upper Alarm Limit button. Used to view upper alarm limits. When this button is pressed at the same time as the Lower Alarm Limit button, menu options are accessible. It is also used to select menu options.

The Lower Alarm Limit button. Used to view lower alarm limits. When this button is pressed at the same time as the Upper Alarm Limit button, menu options are accessible. It is also used to exit menus without change.

Indicators

The AC Power indicator. Lights continuously when the NPB-290 is connected to AC power. This light is off when the monitor is being powered by its internal battery. When lit, it also indicates that the battery is charging.

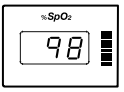
The Low Battery indicator. When 15 minutes or less battery capacity remains, the indicator lights continuously and a low priority alarm sounds.

The Alarm Silence indicator. Lights continuously when an active audible alarm has been silenced. It flashes when alarms are permanently silenced.

The Motion indicator. Lights continuously when the monitor detects motion sufficient enough to affect readings.

- The Pulse Search indicator. Lights continuously prior to initial acquisition of a pulse signal, and during Pulse Search mode. It flashes during loss of pulse.

DESCRIPTION OF VISUAL INDICATORS AND DISPLAYS



The %SpO2 Display. Shows the hemoglobin oxygen saturation level.

The Pulse Amplitude indicator. A 10-segment display that shows the relative pulse amplitude. As the detected pulse becomes stronger, more contiguous segments light with each pulse.

The digital Pulse Rate Display. Shows the pulse rate in beats per minute.

DESCRIPTION OF AUDIBLE INDICATORS

Following are descriptions of NPB-290 audible indicators.

Power-On Self-Test (POST) pass	One 1-second tone indicating that the NPB-290 has been turned on and successfully completed the power-on self-test.
Valid Button Press	A single tone indicating that an appropriate button has been pressed.
Invalid Button Press	A single low-pitched tone indicating that a button has been pressed that is not appropriate for the current state of the monitor.
High Priority Alarm	A high-pitched, fast, pulsing tone indicating loss-of pulse.
Medium Priority Alarm	A medium-pitched, pulsing tone indicating an SpO2 or pulse rate limit violation.
Low Priority Alarm	A low-pitched, slow, pulsing tone indicating a sensor disconnect, low battery, or monitor failure.

Pulse Beep	A single beep sounds for each detected pulse.
Confirmation Tone	Three beeps sound to indicate a successful menu operation.
Alarm Silence Reminder	Three beeps sound at least every 3 minutes as a reminder that the audible alarm has been silenced.
Volume Setting Tone	A continuous tone that is used to adjust the alarm volume.

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QUICK GUIDE TO OPERATION

Basic Operation
Alarm Functions

This *Quick Guide to Operation* section is intended for use by experienced NPB-290 users. First-time users of this instrument should read the entire manual before use.

BASIC OPERATION

The NPB-290 operates on AC power when the hospital-grade power cord is connected to both the monitor and an AC power source (wall outlet).

The monitor will not operate when its internal battery is discharged, even when the monitor is connected to AC power. Since the battery may become discharged during prolonged storage or shipment, it is important to plug the NPB-290 into an AC wall outlet and allow the battery to charge for a few minutes before attempting to turn on the instrument.

Setup

1. With the monitor on a flat, stable surface, plug the female connector end of the hospital-grade power cord into the rear of the monitor.

Note: The supply voltage selector switch allows connection of the monitor to AC power ranging from 100 VAC to 240 VAC. The switch has two positions: one for the 100-120 VAC ("115"), and one for 200-240 VAC ("230"). *Ensure that the supply voltage selector switch on the rear panel is set to the proper voltage.*

2. Verify that the supply voltage selector switch is in the correct position for your location (see note above). Plug the male connector end of the power cord into a properly grounded AC outlet.

WARNING: In the USA, do not connect the monitor to an electrical outlet controlled by a wall switch.

3. Select a Nellcor sensor that is appropriate for the patient being monitored.

4. Attach the sensor to the patient, following the instructions in the sensor directions for use.

WARNING: Do not use an extension cable with the NPB-290 monitor (other than the MC-10 or SCP-10 sensor cable). Use of another sensor extension cable will have an adverse effect on performance. Do not attach to the sensor port any cable that is intended for computer use.

5. Connect the sensor to the end of the MC-10 or SCP-10 cable that has the clear plastic sensor lock. Secure the sensor in place by lowering the sensor lock over the sensor connector. Gently press on the sensor lock until it clicks into place.

6. Connect the other end of the MC-10 or SCP-10 cable into the NPB-290 by gently pushing it straight into the sensor port located on the front of the monitor.

7. Ensure that nothing is placed in front of the monitor's speaker that could interfere with the audible alarm being heard.

Using the Monitor

1. Turn on the NPB-290 by pressing the Power On/Off button. The monitor conducts a power-on self-test (POST) and signals successful completion of the test with a 1-second tone.

WARNING: If you do not hear the POST pass tone, do not use the monitor.

1. During POST, check to see that all display indicators and segments light, then listen for the completion tone. This tone not only indicates the successful completion of POST, it also confirms that the audible alarm is functional.

2. The Pulse Search indicator lights, and the monitor displays zeroes while it searches for a valid pulse. If no sensor is attached, dashes are displayed and the Pulse Search indicator is not lit.

3. When a valid pulse is detected, the NPB-290 begins monitoring.

ADJUST PULSE BEEP VOLUME

The pulse beep volume can be adjusted by pressing either the Adjust Up or Adjust Down buttons located on the right side of the front panel.

ALARM FUNCTIONS

View/Adjust Alarm Limits

To view the current upper alarm limit for SpO_2, press the upper alarm limit button *once*. The upper alarm limit is shown in the %SpO_2 Display. To change the limit, press either the Adjust Up or Adjust Down button until the desired limit is shown in the display.

To view the current upper alarm limit for Pulse Rate, press the upper alarm limit button *twice*. To change the limit, press the Adjust Up or Adjust Down button until the desired limit is shown.

The same view/adjust functions may be performed for *lower* alarm limits by pressing the lower alarm limit button and following the same procedure as described above.

Audible Alarm Silence

WARNING: Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

To silence the audible alarm, press the Audible Alarm Silence button. The indicator lights to show that the alarm has been temporarily silenced.

Adjust Alarm Silence Duration

To adjust the alarm silence duration, press and hold the Alarm Silence button. The current alarm silence duration is shown in the display. Press the Adjust Up or Adjust Down button to change the silence duration to the desired amount of time.

Disabling Audible Alarms

Setting the alarm silence duration to OFF means that no audible alarms will be produced by the monitor.

To set the alarm silence duration to OFF, press and hold the Alarm Silence button and use the Adjust Up button to increase the current setting until "OFF" is displayed. The next time the Alarm Silence button is pressed, the Alarm Silence indicator flashes, indicating that audible alarms have been disabled.

The factory default allows that the alarm silence duration *can* be set to OFF.

Qualified service personnel, following instructions in the service manual, can also configure the monitor to sound an alarm silence reminder. With this reminder activated, three beeps sound at least every 3 minutes while the alarm silence duration is set to OFF.

Adjust Alarm Volume

To adjust the audible alarm volume, press and hold the Alarm Silence button for more than 3 seconds. The current alarm volume is shown in the display and is sounded on the speaker. Press the Adjust Up or Adjust Down button to adjust the volume to the desired level.

SETUP

Unpacking and Inspection
Performance Verification
List of Components
Monitor Setup

UNPACKING AND INSPECTION

Notify the carrier if the shipping carton is damaged. Unpack the NPB-290 and components. If anything is missing or damaged, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

PERFORMANCE VERIFICATION

Before using the NPB-290 for the first time in a clinical setting, you must verify that the monitor is working properly as described in the Power-on Self-test paragraph of the *Start-up and Use* section. If you cannot resolve the problem, contact qualified service personnel or your local Mallinckrodt representative.

LIST OF COMPONENTS

1 Nellcor NPB-290 pulse oximeter

1 Nellcor pulse oximetry cable, Model MC-10 or SCP-10

1 Hospital-grade power cord

1 Operator's manual

1 Nellcor sensor or assortment pack

Optional Accessories

The following items are available from Mallinckrodt for use with this monitor:

- Wall mount plate
- Tilt-stand supports

MONITOR SETUP

General

WARNING: To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING: Disconnect the NPB-290 and Nellcor sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NPB-290 may affect the MRI image; the MRI unit may affect the accuracy of oximetry measurements.

WARNING: To ensure accurate performance and prevent device failure, do not subject the NPB-290 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING: Do not use an NPB-290 monitor, sensor, cables, or connectors that appear to be damaged.

WARNING: The NPB-290 is not defibrillator-proof. However, it may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during use and shortly thereafter.

Setting Up The NPB-290

The NPB-290 operates on AC power when the hospital-grade power cord is connected to both the monitor and an AC power source (wall outlet).

The supply voltage selector switch allows connection of the monitor to AC power ranging from 100 VAC to 240 VAC. The switch has two positions: one for 100-120 VAC ("115"), and one for 200-240 VAC ("230"). *Ensure that the supply voltage selector switch on the rear panel is set to the proper voltage.*

Operating on a discharged battery

The NPB-290 will not operate when its internal battery is discharged, even when the monitor is connected to AC power. Instead, the error code "EEE 04" is displayed. This feature prevents the accidental use of the monitor with a dead battery. The monitor is only capable of indicating a loss of AC power if its internal battery is functional.

The battery may discharge during prolonged storage or shipment. If the monitor has been in storage for more than 2 months, it is important to plug the monitor into an AC outlet and allow the battery to charge for approximately 30 minutes before attempting to operate the instrument on AC power.

To fully charge a dead battery, plug the monitor into an AC wall outlet and allow it to charge for 14 hours.

If transporting the monitor, or if AC power is not available, you may operate the NPB-290 on battery power for a limited amount of time. In that case, skip Steps 2 and 3 below.

1. Place the NPB-290 on a flat surface near the patient. With an optional mounting plate available from Mallinckrodt, the monitor may be mounted to a wall.

2. Plug the female connector end of the power cord into the rear of the monitor as shown in Figure 3. Use only the hospital-grade power cord provided by Mallinckrodt.

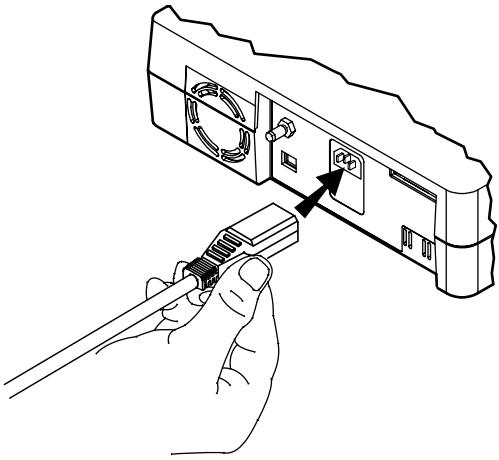

Figure 3: Connecting the Power Cord

3. Verify that the supply voltage selection switch located on the rear of the monitor matches the AC power requirement at your location.

4. Plug the male connector end of the power cord into a properly grounded AC outlet.

WARNING: In the USA, do not connect the monitor to an electrical outlet controlled by a wall switch.

5. Select a Nellcor sensor appropriate for the patient to be monitored (see the *Sensors and Accessories* section of this manual for sensor selection information).

WARNING: Do not use an extension cable with the NPB-290 monitor (other than the MC-10 or SCP-10 sensor cable). Use of another sensor extension cable will have an adverse effect on performance. Do not attach to the sensor port any cable that is intended for computer use.

6. Plug the sensor into the MC-10 or SCP-10 sensor cable, and secure the sensor in place by lowering the plastic sensor lock over the sensor connector until it clicks into place (refer to the MC-10 or SCP-10 directions for use).

7. Plug the MC-10 or SCP-10 cable into the sensor port located on the front of the NPB-290 (as shown in Figure 4).

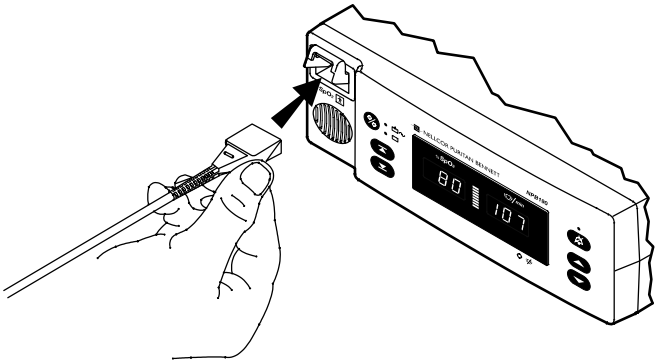

Figure 4: Connecting an MC-10 or SCP-10 Sensor Cable to the NPB-290

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SENSORS AND ACCESSORIES

Selecting a Sensor
Biocompatibility Testing
Performance Considerations
Optional Accessories

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor or sensor cable. Do not use a sensor with exposed optical components.

WARNING: Use only Nellcor sensors and sensor cables with this monitor. Other sensors or sensor cables may cause improper NPB-290 performance.

WARNING: Do not use the NPB-290 or Nellcor sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The NPB-290 may affect the MRI image or the MRI unit may affect the accuracy of oximetry measurements.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: Nellcor Sensors

Sensor	Model	Patient Size
Oxisensor® II oxygen transducers (Sterile, single-use only)	N-25/N-25LF I-20/I-20LF D-20 D-25(L) R-15	<3 or >40 kg 3 to 20 kg 10 to 50 kg >30 kg >50 kg
Oxiband® oxygen transducer (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3 to 40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (reusable, nonsterile)	RS-10	>40 kg
Dura-Y® multisite oxygen transducer (Reusable, nonsterile) For use with the Dura-Y sensor: Ear clip (Reusable, nonsterile) Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)	D-YS D-YSE D-YSPD	>1 kg >30 kg 3 to 40 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

BIOCOMPATIBILITY TESTING

Biocompatibility testing has been conducted on Nellcor sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are, therefore, in compliance with ISO 10993-1.

PERFORMANCE CONSIDERATIONS

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Inaccurate measurements can be caused by:

- incorrect application of the sensor
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- patient movement
- Loss of pulse signal can occur for the following reasons:
- the sensor is too tight
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor

Use only Nellcor sensors and sensor cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to see that the sensor remains properly positioned on the patient.

WARNING: Tissue damage can be caused by incorrect application or duration of use of an SpO_2 sensor. Inspect the sensor site as directed in the sensor directions for use.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

Note: Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- Verify that the sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that tolerates some patient motion.

- Use a new sensor with fresh adhesive backing.

If poor perfusion affects performance, consider using the *Oxisensor* R-15 sensor. It obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This sensor may obtain measurements when peripheral perfusion is relatively poor.

For low peripheral perfusion, consider using the Nellcor RS-10 sensor, which is applied to the forehead or temple, sites that may be spared during peripheral vasoconstriction.

Note: The preceding section pertains to patient and environmental conditions that can be addressed by sensor selection and application. For information regarding the impact of other patient and environmental conditions on oximeter performance, see "Performance Considerations" in the *Start-Up and Use* section of this manual.

OPTIONAL ACCESSORIES

Wall Mount Plate

An optional wall mount plate is available from Mallinckrodt for the NPB-290. This mounting plate fits standard, commercially available GCX wall mount brackets, and is used to securely mount the monitor to a wall.

The plate attaches to the bottom of the NPB-290 monitor as shown in Figure 5. For further instructions regarding connecting the plate to GCX brackets, refer to the illustrated directions for use included with the wall mount plate.

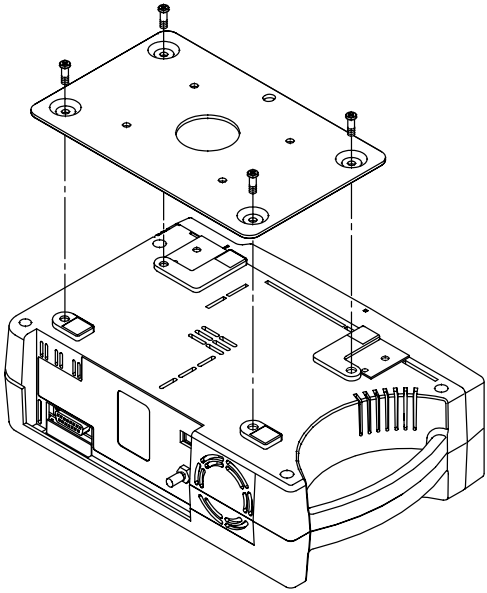


Figure 5: Attaching the Mounting Plate

Tilt-Stand Supports

A pair of tilt-stand supports are available from Mallinckrodt for the NPB-290 monitor. These supports provide the option of tilting the front of the monitor upward in order to view the display at an angle. When not in use, the supports can be folded flat against the bottom of the monitor.

The supports are attached to the NPB-290 as shown in Figure 6.

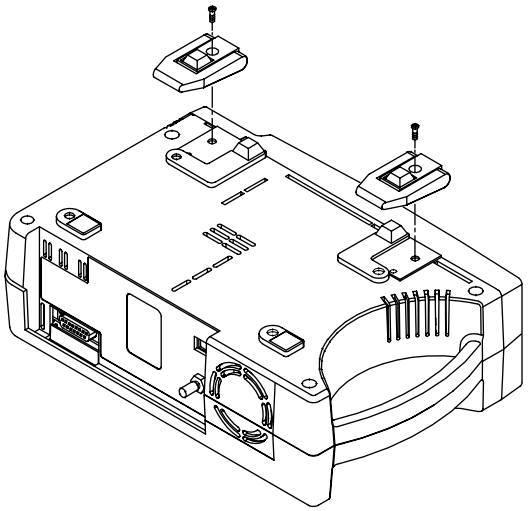


Figure 6: Attaching the Tilt-Stand Supports

START-UP AND USE

Basic Operation
Alarms
Trend Data
Battery Operation
Disposal of Device Components
Performance Considerations

BASIC OPERATION

WARNING: The NPB-290 is a prescription device and is to be operated by qualified personnel only.

WARNING: Do not lift the monitor by the sensor cable or power cord because the cable or cord could disconnect from the monitor, causing the monitor to drop on the patient.

WARNING: The NPB-290 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.

Important! Prior to using the NPB-290, carefully read this manual, accessory directions for use, all precautionary information in boldface type, and all specifications.

Before using the NPB-290 in a clinical setting, you must verify that the monitor is working properly and is safe to use. Proper working condition can be verified by successful completion of the power-on self-test described in the following steps, and by following the instructions contained in "Monitoring" in this section.

Ensure that the voltage selector switch on the rear panel is set to the proper voltage.

Power-On Self-Test (POST)

WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

1. Plug an appropriate Nellcor sensor firmly into the MC-10 or SCP-10 and lower the MC-10 or SCP-10 sensor lock over the sensor connector until it clicks into place. Insert the MC-10 or SCP-10 into the NPB-290 sensor port. Apply the sensor to the patient as described in the sensor directions for use.

2. Turn on the NPB-290 by pressing the Power On/Off button. After a few seconds, the monitor automatically starts a power-on self-test (POST), which tests its circuitry.

Caution: During POST (immediately after power-up), confirm that all display segments and indicators light.

3. While performing POST, the self-test display appears for approximately 2 seconds. During this time:
   - All indicator lights illuminate
   - All segments of all numeric digits light and change from red to green
   - All segments of the Pulse Amplitude Display light

Caution: If any indicator or display element does not light, do not use the monitor. Instead, contact qualified service personnel or your local Mallinckrodt representative.

4. Once the display test portion of POST is complete, the

   NPB-290 software version is displayed for approximately 2 seconds.

   Note: Software version numbers are often needed when calling Mallinckrodt's Technical Services Department or your local Mallinckrodt representative for technical assistance. Write down

the numbers and have them available prior to requesting technical assistance.

5. If the NPB-290 detects an internal problem during the self-test, an error tone sounds and the monitor displays an Error Code and corresponding number (see the *Troubleshooting* section).

6 Upon successful completion of the self-test, the NPB-290 sounds a 1-second tone indicating that the monitor has passed the test.

WARNING: If you do not hear the POST pass tone, do not use the monitor.

In addition to serving as the POST pass verification, the POST pass tone also functions as audible confirmation that the speaker is performing properly. If the speaker does not function, the alarms cannot sound.

If a sensor is connected to the monitor and the patient, the Pulse Search indicator lights and the NPB-290 displays zeroes in its SpO_2 and pulse rate fields while it searches for a valid pulse from a patient. If no sensor is attached, dashes are displayed and the Pulse Search indicator is not lit.

Silencing or Adjusting Pulse Beep Volume

The pulse beep volume can be adjusted within a range of 0-10. At Level 0, the pulse beep volume is silenced; at Level 10, the volume is at its highest setting.

This volume can be adjusted by pressing either the Adjust Up or Adjust Down button located on the right side of the front panel.

Note: The default volume setting can be changed by qualified service personnel by following the instructions described in the NPB-290 service manual.

Monitoring

During monitoring, the NPB-290 displays SpO_2 and pulse rate readings with each pulse beat. %SpO_2 is displayed for values between 0% and 100%. Pulse rates are displayed for values from 20 to 250 beats per minute, and for zero beats per minute.

Note: Pulse rates below 20 (except zero) are displayed as 20, and pulse rates above 250 are displayed as 250. A pulse rate of zero is used to indicate that the monitor is not monitoring a pulse.

A variable-pitched beep sounds once for each pulse. The pitch of this tone corresponds to the measured %SpO_2 at the sensor site. For example, the higher the oxygen saturation, the higher the pitch.

Note: Verify that indicators, display information, and audible sounds, including alarms, are operational, indicating that the monitor is functioning. Each valid button press should generate an appropriate action. Observe movement of the Pulse Amplitude indicator and listen for pulse beeps to verify that measurements are being made.

If any action does not seem appropriate, do not use the monitor. Instead, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

If the acquired pulse is lost during monitoring, the NPB-290 enters Pulse Search.

Pulse Search

During Pulse Search, the monitor attempts to detect a pulse from which to take a measurement.

Note: Pulse Search is a normal function of the monitor, and entering this mode is not necessarily indicative of a lost *patient* pulse.

At Initial Power-Up

Immediately after the NPB-290 displays its software version numbers and POST is completed, the monitor enters Pulse Search (the Pulse Search indicator lights), if a sensor is properly connected to the monitor. During this Pulse Search, the display reads zeroes while the monitor searches for a valid pulse. When a valid pulse is detected, the NPB-290 begins monitoring.

After Taking Measurements

If a pulse was previously acquired and then lost, the NPB-290 enters Pulse Search, and the Pulse Search indicator lights. The display flashes the last detected readings while the monitor searches for a valid pulse. When the monitor considers the pulse "lost," it displays flashing zeroes and a high priority alarm sounds.

When a valid pulse is again detected, the NPB-290 exits pulse search and displays the current readings. The Pulse Search indicator goes out.

Refer to the "Management of the Loss-of-Pulse Alarm" paragraph later in this section for a detailed description of Pulse Search, motion, and the loss-of-pulse alarm.

Automatic Shutdown

The monitor automatically shuts off after 15 minutes, provided all of the following conditions are in effect:

- the monitor is running on its internal battery
- no alarms are present (other than low battery or a non-correctable error)
- no buttons have been pressed, and
- no pulse has been detected

Once a valid pulse is again acquired (within 15 minutes), the instrument begins monitoring again.

ALARMS

Description of Alarms

The NPB-290 has three levels of audible alarms.

1. *High-priority alarm:* Indicated by a fast-rate, high-pitched, pulsing tone. A high-priority alarm sounds after loss-of-pulse is detected.

   Refer to the "Management of the Loss-of-Pulse Alarm" paragraph later in this section for a detailed description of the loss-of-pulse alarm.

2. *Medium-priority alarm:* Indicated by a medium-rate, medium-pitched, pulsing tone. A medium-priority alarm sounds when any measured patient parameter (%SpO_2 or Pulse Rate) moves outside the set alarm limits.

   During a medium-priority alarm, the yellow display turns red and flashes with the patient parameter that violated the limit (%SpO_2 or Pulse Rate).

3. *Low-priority alarm:* Indicated by a slow-rate, low-pitched, pulsing tone. A low-priority alarm sounds during the following conditions:

   - low battery (while operating on battery power)
   - when an SpO_2 cable has disconnected
   - monitor failure
   - 50 seconds after loss of pulse is detected in the presence of continuous motion
   - During a low battery alarm, the Low Battery indicator illuminates and the alarm tone sounds immediately, even if the alarms are silenced or set to OFF.

Adjusting Alarm Limits

WARNING: Each time the monitor is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

Overview

When the NPB-290 is first powered on, alarm limits are set to their power-on default values. Power-on default alarm limits can be changed by qualified service personnel, using the instructions described in the NPB-290 service manual.

You can temporarily change alarm limits from their default values if necessary, as described below. Changes you make remain in effect until you change them again, or until you turn off the NPB-290.

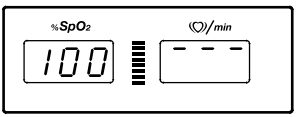
Note: If the monitor resets at any time during operation, for example due to an AC power surge, the monitor will again conduct its power-on self-test (POST) and sound the POST completion tone.

Any alarm limits that have been temporarily changed prior to the reset could revert back to their default values. A reset should occur, check the alarm limit values to ensure that they are appropriate for the patient being monitored.

Viewing Current Alarm Limits

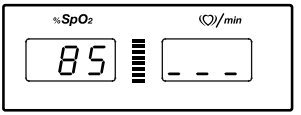
To view the current upper alarm limit value for SpO_2, press the Upper Alarm Limit button.

The number displayed in the %SpO_2 field represents the current SpO_2 upper alarm limit. A series of dashes are displayed in the Pulse Rate field. Since the parameter being displayed is an *upper* limit, these dashes appear in the upper portion of the Pulse Rate display, as shown:



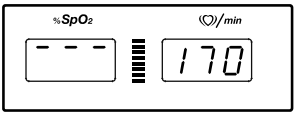
To view the current lower alarm limit value for SpO_2, press the Lower Alarm Limit button.

The number displayed in the %SpO_2 field represents the current SpO_2 lower alarm limit. A series of dashes are displayed in the Pulse Rate field. Since the parameter being displayed is a *lower* limit, these dashes appear in the lower portion of the Pulse Rate display, as shown:



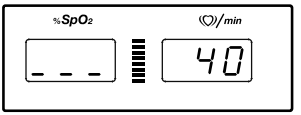
To view the current upper alarm limit value for Pulse Rate, press the Upper Alarm Limit button twice.

The number displayed in the Pulse Rate field represents the current pulse rate upper alarm limit. A series of dashes are displayed in the %SpO_2 field. Since the parameter being displayed is an *upper* limit, these dashes appear in the upper portion of the SpO_2 display, as shown:



To view the current lower alarm limit value for Pulse Rate, press the Lower Alarm Limit button twice.

The number displayed in the Pulse Rate field represents the current pulse rate lower alarm limit. A series of dashes are displayed in the %SpO_2 field. Since the parameter being displayed is a *lower* limit, these dashes appear in the lower portion of the SpO_2 display, as shown:



Changing Alarm Limits

To change an existing alarm limit, first enter the viewing mode for that value, as described earlier in "Viewing Current Alarm Limits." Once the value you wish to change is displayed, press the Adjust Up or Adjust Down button to adjust the value as needed.

Alarm Limits Changed Indicator

If alarm limits are changed from the NPB-290's power-on defaults, a decimal point appears after the displayed value, during patient monitoring, or when alarm limits are viewed. The decimal point remains on the digital display until the NPB-290 is turned off or the limit is returned to its default value.

Adjusting Audible Alarm Silence Duration

WARNING: Do not silence an audible alarm or decrease its volume if patient safety could be compromised.

Alarms can be silenced for a preset period called the *audible alarm silence duration.* The audible alarm silence duration begins when you press and release the Alarm Silence button.

If an alarm condition occurs while the alarm is silenced, the alarm will not sound until the alarm silence duration has ended.

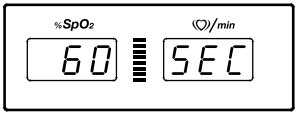
Note: An additional press of the Alarm Silence button reactivates the audible alarm.

If the alarm condition is still present or a new alarm condition occurs after the alarm silence duration has elapsed, an audible alarm sounds.

The power-on default audible alarm silence duration setting is in effect unless it is changed. The power-on default set at the factory is 60 seconds. This default setting can be adjusted by service personnel as described in the NPB-290 service manual.

Viewing Current Alarm Silence Duration

To view the current audible alarm silence duration, press and hold the Alarm Silence button for less than 3 seconds. The display will show the current duration in seconds, as shown:



To adjust the audible alarm silence duration, while holding down the Alarm Silence button, use the Adjust Up or Adjust Down button to set the duration to 30, 60, 90, or 120 seconds, or OFF (Alarm Silence mode). While the alarm is silenced temporarily, the Alarm Silence indicator lights during the silence duration period.

Visual indications of an alarm condition are not affected by silencing the audible alarms.

Disabling Audible Alarms

Setting the alarm silence duration to OFF means that no audible alarms will be produced by the monitor.

To set the alarm silence duration to OFF, press and hold the Alarm Silence button for less than 3 seconds and use the Adjust Up button to increase the current setting until "OFF" is displayed. The next time the Alarm Silence button is pressed, the Alarm Silence indicator flashes, indicating that audible alarms have been disabled.

Visual indications of an alarm condition are not affected by disabling the audible alarms.

The ability to set the alarm silence duration to OFF can be enabled or disabled by qualified service personnel as described in the service manual.

The factory default is that the capability of setting the alarm silence duration to OFF is enabled.

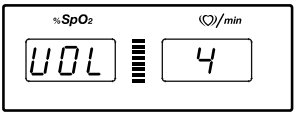
Alarm Silence Reminder

The alarm silence reminder (three beeps) sounds at least every 3 minutes while the alarm silence duration is set to OFF.

The alarm silence reminder may also be disabled by service personnel using the procedures described in the service manual. The factory default is that the reminder is enabled.

Adjusting Audible Alarm Volume

To view the current volume of the audible alarm, press and hold the Alarm Silence button for more than 3 seconds, without touching any other buttons. The display will show the current volume level, as shown:



To adjust the audible alarm volume, while viewing the current alarm volume, press the Adjust Up or Adjust Down button to set the volume level within a volume range of 1 (lowest volume setting) to 10 (highest volume setting). The alarm volume cannot be set to zero.

The audible alarm can only be silenced using the Alarm Silence button, as discussed earlier in this section.

Management of Loss-of-Pulse Alarm

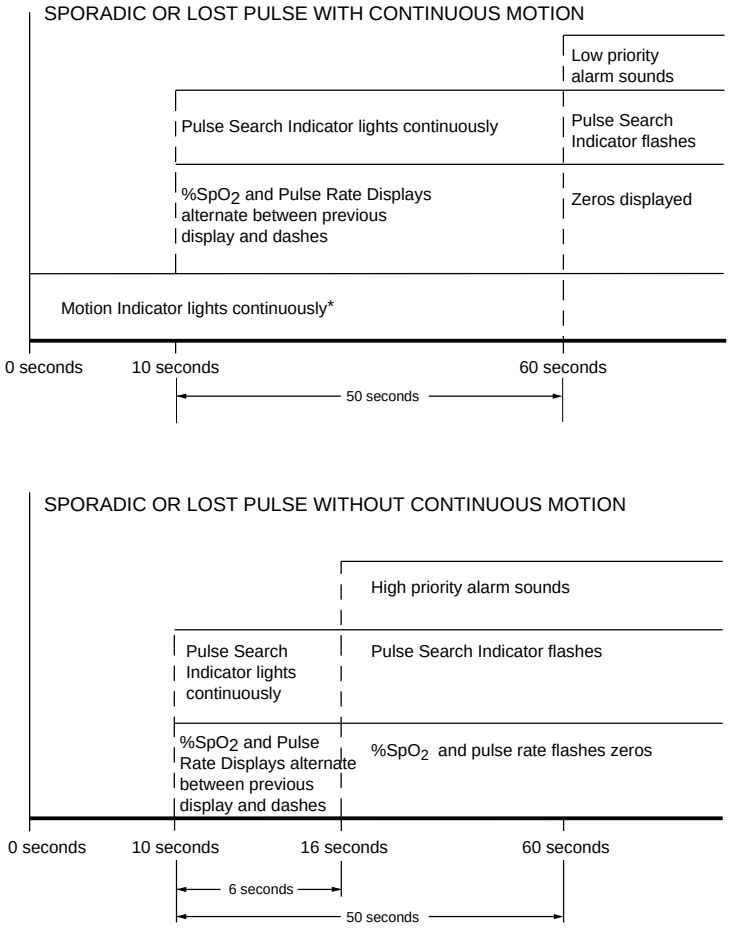
The NPB-290 signal processing is designed to reduce the adverse effects of normal interference associated with motion, low patient perfusion, and spurious electrical or optical signals. Figure 7 illustrates monitor response in sporadic or lost pulse situations with and without continuous motion.

Losing the pulse presents an alarm-management challenge for any oximeter—sometimes it is caused by a clinical emergency, sometimes by signal distortion. When the pulse is lost because of deteriorating patient condition, the oximeter should alarm quickly. However, normal interference can obscure the pulsatile signal. If interference is short-lived, no alarm sounds. Such

alarms are distracting and potentially time-consuming. However, if interference persists, an alarm should notify the attendant.

The NPB-290 loss-of-pulse alarm is designed for use in environments in which the pulse can be obscured by interference. Most loss-of-pulse alarms are attributable to interference from patient motion, which typically is brief.

When the pulsatile signal is lost, the NPB-290's ability to identify interference from motion becomes particularly important because the response of the monitor is determined by the presence or absence of interference from patient motion. Because a spontaneously moving patient can be assumed to have a pulse, as long as continuous motion is detected, the NPB-290 continues to search for the pulse.


SPORADIC OR LOST PULSE WITH CONTINUOUS MOTION
Low priority alarm sounds
Pulse Search Indicator lights continuously
Pulse Search Indicator flashes
%SpO2 and Pulse Rate Displays alternate between previous display and dashes
Zeros displayed
Motion Indicator lights continuously*
0 seconds
10 seconds
60 seconds
50 seconds
SPORADIC OR LOST PULSE WITHOUT CONTINUOUS MOTION
High priority alarm sounds
Pulse Search Indicator lights continuously
Pulse Search Indicator flashes
%SpO2 and Pulse Rate Displays alternate between previous display and dashes
%SpO2 and pulse rate flashes zeros
0 seconds
10 seconds
16 seconds
60 seconds
6 seconds
50 seconds

*If during motion the NPB-295 detects a qualified pulse, the values on the display are updated.

If motion stops at any time during the pulse search mode, and no qualified pulse is detected, the high priority alarm will immediately sound after 6 seconds.

Figure 7: Monitoring Conditions and Alarm Responses

The NPB-290 manages loss-of-pulse alarms as follows, and as illustrated in Figure 7. If the NPB-290 fails to detect at least one qualified pulse during any 10-second period, it enters pulse search mode, the Pulse Search indicator lights, the displays alternate between data and dashes, and the data evaluation period starts.

During that data evaluation period:

- If the patient is *not* moving (for example, because of cardiac arrest, shock, paralysis, anesthesia) and has no qualified pulse for 6 seconds, a high-priority alarm immediately sounds, the Pulse Search indicator flashes, and the data displays flash zeroes.
- If the patient *is* constantly moving, the NPB-290 searches for qualified pulses for up to 50 seconds. Each time a qualified pulse is detected, even during motion, the data displays are updated.
- The NPB-290 returns to normal operation as soon as it detects one of the following: three consecutive qualified pulses (when there is no motion), five consecutive qualified pulses (when there *is* motion), or a total of 10 qualified pulses. Otherwise, at the end of the data evaluation period, the data displays flash zeroes and, if motion is still present, a low-priority alarm sounds; if there is no motion, a high-priority alarm sounds.
- If, during the 50-second data evaluation period, motion stops and no qualified pulse is found for 6 seconds, a high-priority alarm sounds immediately.

NPB-290 alarm management can therefore be considered a three-tier system:

- Normal mode, during which qualified pulses are being detected and the data display is routinely updated.
- Pulse-search mode, during which the Pulse Search indicator lights, the data display alternates between data and dashes, and the data evaluation period is ongoing. The data display is updated when a qualified pulse is detected.
- Loss-of-pulse mode, during which an alarm sounds, the Pulse Search indicator flashes, and the data displays flash zeroes.

Nurse Call Feature

WARNING: The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the monitor, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

The nurse call feature of the NPB-290 works in conjunction with the nurse call system of your institution when the monitor sounds an audible alarm. It is accessed through the data port (pin 11 or 15, as indicated in Table B1, Appendix B).

WARNING: The nurse call feature is not functional whenever the alarms are silenced.

The nurse call feature is available when the NPB-290 is operated on AC power and the monitor has been electronically connected to the hospital's nurse call system. Depending on the method of installation used by the service technicians in your institution, this feature *may* by available when the monitor is running on its internal battery. Qualified service personnel may refer to the NPB-290 service manual for complete connection instructions.

The remote location is signaled anytime there is an audible alarm. If the audible alarm has been turned off, or silenced, the nurse call function is also turned off.

Prior to using the monitor in a clinical setting, test the nurse call feature by creating an alarm condition, then verifying that the hospital's nurse call system is activated.

TREND DATA

The NPB-290 collects patient trend data for oxygen saturation, pulse rate, and pulse amplitude. This information may be retrieved through the NPB-290 data port or cleared using options available in a display menu.

Serial data may be obtained by using a PC or serial printer. Refer to *Appendix B: Data Port Protocol* for a description of available data.

To access the menu options, simultaneously press the Upper and Lower Alarm Limits buttons. Then, using the Adjust Up and Adjust Down buttons, scroll through the available menu options, as follows:

#1: Trend Print. Sends the existing trend data to the NPB-290 serial port.

#2: Trend Clear. Deletes the existing trend data.

#3: Language Selection. Provides the opportunity to change the language of the text sent to the data port to one of the following:

Option 0: English
Option 1: French
Option 2: German
Option 3: Italian
Option 4: Spanish
Option 5: Dutch
Option 6: Portuguese

#4: Baud Rate. Sets the transmission speed of the RS-232 serial data. Options available are:

- 24 (2400 baud)
- 96 (9600 baud)
- 192 (19200 baud)

#5: Serial Port Mode. Selections are as follows:

Option 0: Real -time serial data and trend data

Option 1: Allows use of the NPB-290 with Nellcor central monitoring stations

Option 2: For clinical use with N-200 monitors, fast/slow emulation

Menu Items 6 and 7 are non-functional.

Menu Items 8 and beyond are for use only by qualified service technicians. Information about these options is available in the NPB-290 service manual.

BATTERY OPERATION

The NPB-290 has an internal battery that may be used to power the monitor during transport or when AC power is not available. A new, fully charged battery provides a minimum of 8 hours of monitoring time if there are no alarms or serial or analog output devices connected.

Note: Whenever the monitor is connected to AC power, the battery is being charged. Therefore, it is recommended that the monitor remain connected to AC power when not in use. This makes available a fully charged battery for use at any time.

A completely discharged battery can be fully recharged in approximately 14 hours, whether the monitor is turned on or off.

Since the monitor cannot operate with a dead battery, before attempting to turn on an NPB-290 whose battery charge has been depleted, first plug the monitor into an AC outlet to allow the battery to charge for a few minutes. The monitor then may be powered on.

Low Battery Indicator

When 15 minutes or less of monitoring time is available on the existing battery charge, the Low Battery indicator lights and a low priority alarm sounds. This alarm is unsilenceable while running on battery power. Connect to AC power to silence the alarm.

Note: If the AC voltage selector switch on the rear panel does not match your AC voltage source, the monitor may run on battery power, even though it is plugged in, which will eventually result in a low priority alarm and a lighted low battery indicator. Ensure that the switch setting matches your AC voltage source.

If the monitor is not connected to AC power within approximately 15 minutes, it shuts down.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter.

It is recommended that the internal battery be replaced by qualified service personnel every 24 months.

Caution: If the NPB-290 is to be stored for a period of 2 months or longer, remove the battery from the monitor prior to storage. Recharge the battery when it has not been charged for 2 or more months.

DISPOSAL OF DEVICE COMPONENTS

Caution: Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

PERFORMANCE CONSIDERATIONS

Impact of Patient Conditions on Monitor Readings

Certain patient conditions can affect the measurements of the NPB-290 and cause the loss of the pulse signal.

WARNING: Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Inaccurate measurements can be caused by:

- excessive patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- significant levels of dysfunctional hemoglobins
- defibrillation

Ambient environmental conditions and sensor application errors, which can affect pulse oximetry readings, are discussed in the

Sensors and Accessories section of this manual and in the sensor directions for use.

The effects of electromagnetic interference on oximetry readings are discussed in the *Troubleshooting and Maintenance* section of this manual.

(Balnk Page)

TROUBLESHOOTING AND MAINTENANCE

Troubleshooting
EMI Interference
Obtaining Technical Assistance
Returning the NPB-290
Maintenance

TROUBLESHOOTING

WARNING: if you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

If you experience a problem while using the NPB-290 and are unable to correct it, contact qualified service personnel or Mallinckrodt's representative. The NPB-290 service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

Following is a list of possible errors and suggestions for correcting them.

1. **There is no response to the Power On/Off button.**
   - If operating on AC power, ensure that the supply voltage selector switch is set to the proper voltage.
   - If operating on AC power, the fuse may be blown. Notify service personnel to check and, if necessary, replace the fuse.
   - If operating on battery power, the battery may be missing or discharged. If the battery is discharged, notify service personnel to charge or replace the battery.
2. **One or more display segments or indicators do not light during the power-on self-test.**

- Do not use the NPB-290; contact qualified service personnel or your local Mallinckrodt representative.

3. **The monitor does not sound a tone indicating successful completion of POST.**

   - The monitor has failed the power-on self-test. Do not use the monitor. This tone not only indicates the successful completion of POST, but it confirms that the audible alarm is functional. Contact qualified service personnel or your local Mallinckrodt representative.

4. **The Pulse Search indicator is lit for more than 10 seconds while the sensor is connected to the patient.**

   - Check the sensor directions for use to determine if an appropriate sensor is being used and if it is applied properly. Check sensor and extension cable connections. Test the sensor on someone else. Try another sensor or extension cable.
   - Perfusion may be too low for the NPB-290 to track the pulse. Check the patient. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
   - Excessive patient motion may be preventing the NPB-290 from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied, and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement (for example, an adhesive sensor).
   - The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary.
   - Excessive environmental motion or electromagnetic interference may be preventing the NPB-290 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

5. **The Pulse Search indicator lights *after* successful measurements have been made.**

   - Check the patient.
   - Perfusion may be too low for the NPB-290 to track the pulse. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
   - Excessive patient motion may be preventing the NPB-290 from tracking the pulse. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement (for example, an adhesive sensor).
   - The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary.
   - Excessive environmental motion or electromagnetic interference may be preventing the NPB-290 from tracking the pulse. Remove the source of interference or try to stabilize the environment, or do both.

6. **The letters EEE, followed by a number, appear on the display.**

   - This is an error code. To confirm, press the Power On/Off button to turn the monitor off, then press the button again to turn it back on. If the display shows the error code once again, record the number and provide that information to qualified service personnel, or your local Mallinckrodt representative.
   - Error Code "EEE 4" is displayed when the battery is discharged to a critically low level. Check to ensure that the voltage selector switch on the rear panel is set to the proper voltage for your location.
   - Turn the monitor off and let it charge for about 10 minutes and then turn the unit back on. If the error code is still present, turn the unit off and let it continue to charge. If the monitor has been charged for 30 minutes and the error code is still present, notify service personnel.

EMI INTERFERENCE

Caution: This device has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN60601-1-2:1994, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The NPB-290 is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the offending equipment.
- Increase the separation between the offending equipment and this equipment.

The NPB-290 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity.

If assistance is required, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative.

OBTAINING TECHNICAL ASSISTANCE

For technical information and assistance, or to order parts or a service manual, contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative. The service manual includes block diagrams and a parts list required by qualified personnel for servicing the NPB-290.

When calling Mallinckrodt's Technical Services Department or your local Mallinckrodt representative, you may be asked to tell the representative the software version numbers of your NPB-290.

The software versions appear on the monitor display during the power-on self-test. Write the numbers down and have them available whenever requesting technical assistance.

Returning The NPB-290

Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative for shipping instructions including a Returned Goods Authorization (RGA) number. It is not necessary to return the sensor. Pack the NPB-290 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the NPB-290 by any shipping method that provides proof of delivery.

MAINTENANCE

Service

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

The NPB-290 requires no calibration.

The battery should be replaced at least every 24 months. Refer to the NPB-290 service manual for the battery changing procedure.

If service is necessary, contact qualified service personnel or your local Mallinckrodt representative.

Periodic Safety Checks

It is recommended that the following checks be performed every 24 months:

- Inspect the equipment for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.

Performance Verification

If the monitor has been visibly damaged or subjected to mechanical shock (for example, when dropped), qualified service personnel should perform the procedure in the *Performance Verification* section of the NPB-290 service manual.

Cleaning

WARNING: Do not spray, pour, or spill any liquid on the NPB-290, its accessories, connectors, switches, or openings in the chassis.

The NPB-290 may be *surface-cleaned* by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the monitor.

The surface of the monitor may be *disinfected* using a soft cloth saturated with one of the following solutions:

- 10% chlorine bleach in water
- gluteraldehyde (cidex or equivalent)

Before attempting to clean an SpO_2 sensor, read the directions for use enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor.

SPECIFICATIONS

Performance
Electrical
Environmental Conditions
Environmental Protection
Physical

PERFORMANCE

Measurement Range

SpO_2
0–100%

Pulse Rate
20–250 beats per minute (bpm)

Accuracy

SpO_2

Adults	70–100%	±2 digits
	0–69%	unspecified
Neonates	70–100%	±3 digits
	0–69%	unspecified

Note: Accuracies are expressed as plus or minus "X" digits (oxygen saturation percentage points) between saturations of 70–100%. This variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population. All accuracy specifications are based on testing the subject monitor on healthy adult volunteers in induced hypoxia studies across the specified range. Adult accuracy is determined with *Oxisensor II* D-25 sensors. Neonatal accuracy is determined with *Oxisensor II* N-25 sensors. In addition, the neonatal accuracy specification is adjusted to take into account the theoretical effect of fetal hemoglobin in neonatal blood on oximetry measurements.

Pulse Rate
20–250 bpm ±3 bpm

Note: Pulse Rate accuracy is expressed as ±3 bpm across the display range. This variation equals ± one standard deviation (1SD), which encompasses 68% of the population.

Pulse Rate Display Update Frequency

The Pulse Rate Display updates in less than 2.5 seconds with a 1-second change in SpO_2-derived pulse rate from 30 pulses per minute (ppm) to 200 ppm.

Immunity

Radiated

The NPB-290 is immune to radiated radio-frequency electromagnetic fields of up to 3 volts per meter from 80 MHz to 1 GHz.

Conducted

The NPB-290 is immune to conducted radio-frequency electromagnetic energy of up to 3 volts from 150 kHz to 80 MHz.

ELECTRICAL

Instrument

Power Requirements
100-120 VAC
200-240 VAC
50-60 Hz
20 VA
Fuse Rating: 0.5 Amperes, slow blow

Battery

Type
Lead-acid

Battery Capacity

A minimum of 8 hours with a new, fully-charged battery under the following conditions: no alarms and no analog or serial output devices attached. A completely discharged battery can be fully recharged in approximately 14 hours.

Maximum charge/discharge cycles: 400

ENVIRONMENTAL CONDITIONS

Operating Temperature

Instrument
5 to 40°C

Sensor
Within physiologic range for specified accuracy

Transport/Storage Temperature

(in shipping carton)
-20 to 70°C

(not in shipping carton)
-20 to 60°C

Humidity

Operating
15-95% noncondensing

Storage (unboxed)
15-95% noncondensing over temperature range of -20° C to 60° C

Altitude

Operating
-1280 ft. to 12,000 ft. (-390 m to 3,658 m) [1060 hPa to 700 hPa]

Storage
-1280 ft. to 15,000 ft. (-457 m to 4,573 m) [1060 hPa to 500 hPa]

ENVIRONMENTAL PROTECTION

Mallinckrodt recommends that customers or technical services personnel follow local governing ordinances and recycling instructions regarding disposal or recycling of battery or other device components.

PHYSICAL

Weight

5.5 lbs.
2.5 kg

Size

3.3 in. H x 10.4 in. W x 6 .8 in. D
8.4 cm x 26.4 cm x 17.3 cm

Equipment Classification

(IEC 601-1 / CSA 601.1 / UL 2601-1)

Type of Protection
Class 1 (on AC power)
Internally powered (on battery power)

Degree of Protection
Type BF - applied part

Enclosure Degree of Protection from Liquid Ingress
IPX1

Mode of Operation
Continuous

Emissions Compliance
CISPR 11, Group 1, Class B equipment
EN55011 Emissions Classification

APPENDIX A: PRINCIPLES OF OPERATION

OXIMETRY OVERVIEW

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO_2. During manufacturing, the mean wavelength of the red LED is encoded in a resistor in the sensor.

During monitoring, the instrument's software reads this resistor and selects coefficients that are appropriate for the wavelength of that sensor's red LED; these coefficients are then used to

determine SpO_2. This resistor is read when the monitor is turned on, periodically thereafter, and each time a new sensor is connected.

Additionally, to compensate for differences in tissue thickness, the intensity of the sensor's LEDs are adjusted automatically.

Functional versus Fractional Saturation

This monitor measures functional saturation — oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation — oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\%\,\text{carboxyhemoglobin} + \%\,\text{methemoglobin})} \times 100$$

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation (Figure 8): pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin.

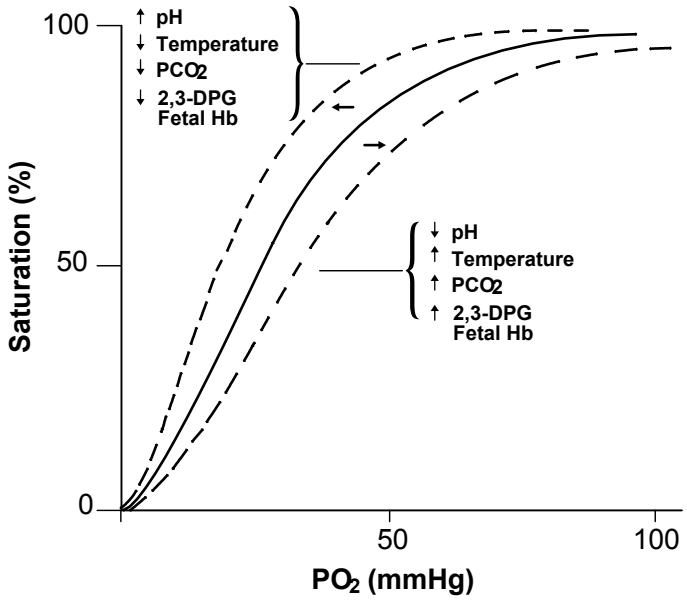


Figure 8: Oxyhemoglobin Dissociation Curve

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APPENDIX B: Data Port Protocol

Overview
Trend Data
Connecting to the Data Port
Real-Time Display Format
Patient Data and Operating Status
Nurse Call

OVERVIEW

Patient data can be obtained through the data port on the back of the NPB-290 by connecting it to an attached PC or serial printer.

When connecting the NPB-290 to a printer or PC, verify proper operation before clinical use. Both the NPB-290 and the printer or PC must be connected to a grounded AC outlet.

Any printer or PC connected to the monitor's data port must be certified according to IEC Standard 950. All combinations of equipment must be in compliance with IEC Standard 601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 601-1-1 and the electromagnetic compatibility system standard IEC Standard 601-1-2.

TREND DATA

The NPB-290 collects patient trend data for oxygen saturation, pulse rate, and pulse amplitude. This information may be retrieved through the NPB-290 data port or cleared using options available in a display menu.

To access the menu options, simultaneously press the Upper and Lower Alarm Limits buttons for at least 3 seconds, until Option 1 appears on the display. Then, using the Adjust Up and Adjust Down buttons, you may scroll through the available menu options, as follows:

#1: Trend Print. Prints a hard copy of the existing trend data available.

#2: Trend Clear. Clears the existing trend data, but does not erase the information. Note: To activate, press the Upper Alarm Limit button.

#3: Language Selection. Provides the opportunity to change the language to one of the following:

Option 0: English

Option 1: French

Option 2: German

Option 3: Italian

Option 4: Spanish

Option 5: Dutch

Option 6: Portuguese

#4: Baud Rate. Allows the interconnection to various printers.

#5: EPP Mode. Selections are as follows:

Option 0: Printout in real-time ASCII characters

Option 1: For use with Nellcor Oxinet II units and with Score™ software.

Note: When using Score™ software use the latest version. Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative to determine the latest version of Score software.

Option 2: For clinical use with N-200 monitors, fast/slow emulation

Menu Items 6 and 7 are non-functional.

Menu Items 8 and beyond are for use only by qualified service technicians. Information about these options is available in the NPB-290 service manual.

CONNECTING TO THE DATA PORT

The NPB-290 data port may be connected to the printer or PC by using a cable terminated with an AMP connector (AMP part number 747538-1), ferrule (AMP part number 1-747579-2), and

compatible pins (AMP part number 66570-2). The cable should be no more than 25 feet (7.6 meters) in length. The external ITE (Information Technology Equipment) device must be certified to UL-1950 or IEC-60950.

The cable used must have a braided shield providing 100% coverage, such as a Belden cable (Belden part number 9609) or equivalent. The shield must have a 360-degree connection to the metal shell on the NPB-290's DB-15 connector and to the connector on the PC or serial printer. Do not create sharp bends in the cable, as this may tear or break the shielding.

The pinouts (as illustrated in Figure 9) for the data port are listed in Table 2.

Table 2: Data Port Pinouts

Pin	Signal Name
1	RxD+ (RS-422[+] input)
2	RxD_232 (RS-232 input)
3	TxD_232 (RS-232 output)
4	TxD+ (RS-422[+] output)
5	Signal Ground (isolated from Earth Ground)
6	AN_SPO2 (analog saturation output)
7	NC_NO (relay closure nurse call, normally open)
8	NC_NC (relay closure nurse call, normally closed)
9	RxD- (RS-422 [-] input)
10	Signal Ground (isolated from Earth Ground)
11	Nurse Call (232-level output)
12	TxD- (RS-422 [-] output)
13	AN-PULSE (analog pulse rate output)
14	AN-PLETH (analog pleth wave output)
15	NC-COM (relay closure nurse call common lead)

GND is ground, TxD represents the Transmit Data line, and RxD is the Receive Data line.

The pin layouts (as viewed from the rear panel of the NPB-290) are illustrated in Figure 9. The conductive shell is connected to earth ground when connected to a PC or printer.

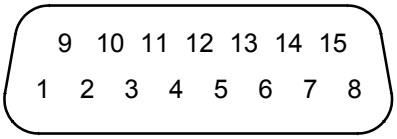

Figure 9: Serial Port Pin Layout

Pins 2, 3, and 5 provide data in RS-232 format.

Pins 1, 4, 9, and 12 provide data in RS-422 format. TxD+ and TxD- are the differential transmit data pair. RxD+ and RxD- are the differential receive pair.

No hardware flow control is used. However, XON/XOFF flow control is supported.

REAL-TIME DISPLAY FORMAT

Real-time data is continuously sent to the data port on the back of the NPB-290. Patient data can be obtained through the data port by connecting it to an attached PC or serial printer. When a real-time printout or display is being transmitted to a printer or PC, a new line of data is displayed every 2 seconds. Column headings are displayed or printed after every 25 lines, or if one of the values in the column heading changes.

Data cannot be obtained if the NPB-290 is operating on battery power.

Note: If the data output stops transmitting, turn the power off and back on again or, if connected to a PC, send an XON (Ctrl-q) to reset the monitor.

An example of a real-time printout is shown in Figure 10.

NPB-290	VERSION 1.0.0.2		CRC: XXXX	SpO2 Limit: 30-100%		PR Limit: 100-180BPM
TIME		%SPO2	BPM	PA	Status	
12-NOV-97 14:00:05		100	120	50		
12-NOV-97 14:00:07		100	124	50		
12-NOV-97 14:00:09		100	190	52		PH
12-NOV-97 14:00:11		100	190*	50		PH
12-NOV-97 14:00:13		100	190*	51		PH
12-NOV-97 14:00:15		100	190*	50		PH
12-NOV-97 14:00:17		100	190*	50		PH
12-NOV-97 14:00:19		100	190*	51		PH
12-NOV-97 14:00:21		100	190*	53		PH LB
12-NOV-97 14:00:23		100	190*	50		PH LB
12-NOV-97 14:00:25		100	190*	50		PH LB
12-NOV-97 14:00:27		---	---	---	SD	LB
12-NOV-97 14:00:29		---	---	---	SD	LB
12-NOV-97 14:00:31		---	---	---	SD	
12-NOV-97 14:00:33		---	---	---	SD	
12-NOV-97 14:00:35		---	---	---	SD	
12-NOV-97 14:00:37		---	---	---	SD	
12-NOV-97 14:00:39		---	---	---	SD	
12-NOV-97 14:00:41		---	---	---	SD	
12-NOV-97 14:00:43		---	---	---	SD	
12-NOV-97 14:00:45		---	---	---	SD	
12-NOV-97 14:00:47		---	---	---	SD	
12-NOV-97 14:00:49		---	---	---	SD	
NPB-290	VERSION 1.0.0.1		CRC: XXXX	SpO2 Limit: 30-100%		PR Limit: 100-180BPM
TIME		%SPO2	BPM	PA	Status	
12-NOV-97 14:00:51		---	---	---	SD	
NPB-290	VERSION 1.0.0.1		CRC: XXXX	SpO2 Limit: 80-100%		PR Limit: 100-180BPM
TIME		%SPO2	BPM	PA	Status	
12-NOV-97 14:00:53		79*	59*	50	SL PL LB	
12-NOV-97 14:00:55		79*	59*	52	PS SL PL LB	

Figure 10: Real-Time Printout

Column Headings

Every 25th line of the data is a column heading.

NPB-290	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%		PR Limit: 100-180BPM
TIME	%SPO2	BPM	PA	Status	

A column heading is also displayed whenever a value of the column heading is changed. There are three column heading lines shown in Figure 10. Using the top row as the starting point there are 25 lines before the second column heading is printed. The third column heading was displayed because the SpO_2 limits changed from 30-100% to 80-100%.

Data Source

NPB-290	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%		PR Limit: 100-180BPM
TIME	%SPO2	BPM	PA	Status	

Data in the highlighted box above represents the model number of the monitor, in this case the NPB-290.

Software Revision Level

NPB-290	VERSION 1.0.0.1		CRC: XXXX		SpO2 Limit: 30-100%		PR Limit: 100-180BPM
TIME		%SPO2	BPM		PA	Status	

The next data field tells the user the software level, (Version 1.0.0.1) and a software verification number (CRC: XXXX). Neither of these numbers should change during normal operation. The numbers may change if the monitor is serviced and receives a software upgrade.

Alarm Limits

NPB-290	VERSION 1.0.0.1		CRC: XXXX		SpO2 Limit: 30-100%		PR Limit: 100-180BPM
TIME		%SPO2	BPM		PA	Status	

The last data field in the top line indicates the high and the low alarm limits for %SpO_2 and for the pulse rate (PR). In the example above, the low alarm limit for SpO_2 is 30% and the high alarm limit is 100%. Pulse Rate alarm limits are 100 to 180 bpm.

Column Headings

NPB-290	VERSION 1.0.0.1		CRC: XXXX		SpO2 Limit: 30-100%		PR Limit: 100-180BPM
TIME		%SPO2	BPM		PA	Status	

Actual column headings are in the second row of the column heading line. Patient data that is presented in the chart, from left to right, is the time that the patient data on the row was obtained, the current %SpO_2 value being measured, the current Pulse Rate in beats per minute (BPM), the current Pulse Amplitude (PA), and the operating status of the NPB-290.

PATIENT DATA AND OPERATING STATUS

Time

TIME	%SPO2	BPM	PA	Status
12-NOV-97 14:00:05	100	120	50	

The Time column represents the NPB-290 real-time clock.

Patient Data

NPB-290	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 100-180BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-97 14:00:05	100	190*	50	

Patient data is highlighted in the display above. Parameter values are displayed directly beneath the heading for each parameter. In this example the %SpO_2 is 100, and the pulse rate is 190 beats per minute. The "*" next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available three dashes (- - -) are displayed.

PA is an indication of pulse amplitude. The number can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information as an indication of a change in pulse volume, relative pulse strength or circulation.

Operating Status

NPB-290	VERSION 1.0.0.1	CRC: XXXX	SpO2 Limit: 30-100%	PR Limit: 100-180BPM
TIME	%SPO2	BPM	PA	Status
12-NOV-97 14:00:11	100	190*	50	PH

The Status column indicates alarm conditions and operating status of the NPB-290. In this example, the PH means that the pulse rate upper alarm limit (Pulse High) has been exceeded. A complete listing of the status codes is listed in Table 3. As many as four codes can be displayed at one time in the Status column.

Table 3: Status Codes

Code	Meaning
AO	Alarm Off
AS	Alarm Silence
LB	Low Battery
LP	Loss of Pulse
MO	Patient Motion
PH	Pulse Rate High Limit Alarm
PL	Pulse Rate Low Limit Alarm
PS	Pulse Search
SH	Sat High Limit Alarm
SL	Sat Low Limit Alarm
SD	Sensor Disconnect

Note: A sensor disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the printout.

TREND DATA PRINTOUT

The format of data displayed when a trend printout is requested is similar to that of the real time data. The only differences are that "TREND" is displayed in the top row instead of the "CRC: XXXX" software verification number and there is no "Status" column.

Readings are displayed in 2-second intervals. The values on each row are an average for the 2-second period.

At the end of the printout an "Output Complete" line indicates that the transmission was successful. If the "Output Complete" line is not present, a corruption of the data may have been detected and the data should be ignored.

```
NPB-290      VERSION 1.0.0.1          TREND          SpO2 Limit: 30-100%      PR Limit: 100-180BPM
TIME                          %SPO2        BPM          PA
22-NOV-97 14:00:05              100         120         150
22-NOV-97 14:00:07              100         121         154
22-NOV-97 14:00:09              100         120         150
Output Complete
```

Figure 11: Trend Data Printout

Once a trend printout has begun, the NPB-290 must be turned off and back on again before a new trend printout can begin. A trend printout cannot be aborted without turning off the NPB-290 or the printer.

TREND DATA OPERATION

Whenever the NPB-290 is turned on, it stores a "data point" in memory every 2 seconds (regardless of whether the NPB-290 is monitoring a patient or not). Up to 50 alarm limit changes will also be stored in trend data. The NPB-290 can store up to 24 hours of trend data. The 24 hours of stored trend data is available for downloading to Score™ software for 45 days. There are no limitations for displaying or printing data.

Caution: Changing alarm limit settings uses up trend memory space. Change alarm limits only as needed.

Note: Trend memory always contains the MOST RECENT 24 hours of data, with newly collected data over-writing the oldest data on a rolling basis. The NPB-290 continues to record data points as long as the monitor is powered on, with "blank" data points collected if no sensor is connected to the monitor or patient. "Blank" data will over-write older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your monitor off when you are not monitoring a patient, and that you download the trend memory, using Score software, before it fills up and over-writes the old data with new data (or "blank" data).

Note: When using Score™ software use the latest version. Contact Mallinckrodt's Technical Services Department or your local Mallinckrodt representative to determine the latest version of Score software.

If battery power is disconnected or depleted, trend data and user settings will be lost. All data is stored with error detection coding. If data stored in memory is found to be corrupted, it is discarded.

NURSE CALL

The NPB-290 provides two different types of nurse call interfaces; an RS-232 level and relay closure. The RS-232 level nurse call function only operates when the monitor is connected to AC power. It will not operate when running on battery. The relay-based nurse call function is available when the monitor is operating either on AC power or when powered by battery.

The remote location is signaled anytime there is an audible alarm. If the audible alarm has been turned off, or silenced, the nurse call function is also turned off.

Pin 11 on the data port is the RS-232 level nurse call signal and pin 5 is ground (see Table B1). When there is no alarm condition, the voltage between pins 10 and 11 is -5 to -12 VDC. Whenever the monitor is in an alarm condition, the output between pins 10 and 11 is +5 to +12 VDC.

Pins 7 and 15 provide a relay that closes when an alarm is sounding on the monitor. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays.

ANALOG OUTPUTS

The NPB-290 data port also provides analog voltage outputs between pins 6, 13, 14, and ground (pin 10). The voltage represents a specific measured parameter's current value. The voltage differential varies proportionally from 0 to 1 volt as the pin's parameter varies over its full range of values, as indicated in Table 4.

Table 4: Analog Pinouts

Pin	Parameter	Parameter Range
6	%SpO_2	0 - 100
13	Pulse rate	0 - 250
14	Pleth wave	0 - 255

For example, as the current value of %SpO_2 varies from 0 to 100%, the voltage from pin 6 to ground (pin 10) would vary from 0 to 1 volt. A voltage of .94 volts indicates a current %SpO_2 value of 94.

Calibration of the analog output and the attached device can be performed by qualified service personnel using the procedure described in the NPB-290 service manual.